

**REMARKS/ARGUMENTS**

The specification, at page 1 at line 5, at page 6 at line 3, and at page 9 at line 1, has been amended to insert new section headings. Page 9 at line 1 has been amended to insert the Brief Description of the Drawings heading and related text.

Claims 1, 2, 4–11, 14–18, 21–25 and 27–30 are pending in the captioned application. Claims 2, 15, 16, 27, 29 and 30 have been amended.

Applicants respectfully assert that all amendments are fairly based on the specification and include no new matter. Entry is respectfully requested.

The Examiner has objected to the application as not complying with the “sequence rules even though the sequences have been entered by the Scientific and Technical Information Center (see attached ‘Notice to Comply’).”

In response, Applicants provide a new “Sequence Listing” in electronic and paper format and have amended the specification to insert the appropriate sequence identifiers.

The Examiner has stated, “applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.”

Applicants are unsure as to whether this needs response, inasmuch as the instant application claims priority through the PCT WO 00/55364 to European Patent Application No. 99301933.0 filed March 12, 1999. Such is clearly stated in the specification filed with this application. Should the Examiner require additional information, it is requested that the Examiner be specific about what is required.

Regarding the Information Disclosure Statement, the Examiner has stated, “the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(l) states, ‘the list may not be incorporated into the specification but must be submitted in a separate paper.’ Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.”

Applicants are mindful of this and submit simultaneously herewith form PTO-1449 citing the references for consideration by the Examiner.

The Examiner has rejected Figure 1 of the drawings under 37 C.F.R. § 1.83(a) as it “it fails to show the hybridization patterns. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing.”

In response, Applicants respectfully assert that such objection is improper; inasmuch as the captioned application was filed pursuant to 35 USC 371 and is not subject to the requirements of 37 CFR 1.83. Further, the instant drawings provided by the International Bureau presumptively comply with PCT Rule 11 and should be acceptable. The “USPTO may not impose requirements beyond those imposed by the Patent Cooperation Treaty (e.g. Rule 11)” (MPEP 1893.03(f)).

The above MPEP section does permit the Examiner to require new drawings if the “drawings were published without meeting the requirements of the PCT.” However, no such rejection was raised here, and Applicants will not respond to a rejection which was not raised. Applicants respectfully assert that the drawings filed with the PCT comply with Rule 11.

The Examiner states, “the application contains sequence disclosures...that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in

37 CFR 1.821 (a)( 1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.”

In response, Applicants reiterate that they have, concurrently herewith, amended the specification to insert the sequence identification numbers and to insert the attached sequence listing. Applicants respectfully submit that this overcomes the Examiner's rejection.

The Examiner has objected to the use the trademark 'MetaPhor' (page 119, line 12), stating, "trademarks should be capitalized wherever they appear and be accompanied by the generic terminology."

In response, Applicants have amended the specification to recite that 'MetaPhor' is a trademark by the superscript notation TM; Applicants respectfully assert that the generic terminology as contained directly after the recitation of the trademark as "agarose gel". Further, while Applicants are mindful that trademarks should be capitalized, Applicants believe that the 'MetaPhor' trademark contains a capital 'M' and a capital 'P' and is not ordinarily capitalized in its usage.

The Examiner has referred to 37 C.F.R. § 1.77(b) as providing a “preferred layout” for the specification of a utility patent application.

In response, Applicants have amended the specification and have replaced the heading “**INTRODUCTION**” with “**BACKGROUND OF THE INVENTION**” at page 1, line 5; at page 6, line 3, the heading “**BRIEF SUMMARY OF THE INVENTION**” has been inserted; at page 9, directly following the table, the heading “**BRIEF DESCRIPTION OF THE DRAWINGS**” with the accompanying text has been inserted; and the title “**DETAILED DESCRIPTION OF THE INVENTION**” immediately follows the text of the description of drawings. The claims immediately follow the detailed description. Applicants decline, at this point, to include the other headings, as Applicants do not believe it is proper to require insertion of irrelevant headings.

The Examiner has objected to claim 16 stating, “ ‘selected from’ should be replaced with Markush type language...”

In response, Applicants have amended claim 16 to recite the proper Markush language.

The Examiner has rejected claims 1, 2, 4–11, 15 and 29 under 35 U.S.C. § 112, second paragraph, as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.”

Specifically, the Examiner states, “the terms ‘affected DNA’ and ‘unaffected DNA’ render claims 1, 2, 4–11, and 29 indefinite. It is unclear as to which criteria is utilized to determine which DNA is ‘affected’ or ‘unaffected’.”

In response, Applicants point out that the terms “affected” and “unaffected” are defined at page 2, lines 5–17. Applicants believe that use of such terms is proper inasmuch as it is well understood principle of patent law that a patentee may be his own lexicographer. Applicants respectfully assert that the definitions provided in the cited sections are sufficient to render the claim clear and unambiguous to one skilled in the art.

In view of the foregoing, Applicants respectfully assert the Examiner’s rejections cannot be sustained and should be withdrawn.

The Examiner further states, “claim 15 recites a formula comprising the limitations ‘n!’ and ‘r!’ ” and continues, “there is insufficient antecedent basis for this limitation in the claim. Amending the claim to define the limitations ‘n!’ and ‘r!’.”

In response, Applicants respectfully submit that the terms “n” and “r” are defined in claim 14 and the use of the “!” is the mathematic factorial operator. Hence, Applicants respectfully submit that one skilled in the art would readily understand what is meant in the claim by the recitations “n!”, “r!” and “(n-r)!”.

In view of the foregoing, Applicants respectfully assert the Examiner’s rejections cannot be sustained and should be withdrawn.

Regarding claim 29, the Examiner states, “the phrase ‘comprises steps a), b) and c) one or more time’ renders claim 29 indefinite.” The Examiner continues, “amending the claim to insert an active step (e.g. performing) would obviate the rejection.”

In response, Applicants have amended claim 29 to recite “performing” after “comprises” and before “steps”. Applicants respectfully submit that this amendment obviates the Examiner’s rejection which should be withdrawn.

The Examiner has rejected claims 1, 2, 4–11, 14–16, 23–25, and 29 under 35 U.S.C. § 102(e) as being “anticipated by Wagner, Jr. (US 6,329,147 B1 December 11, 2001).” Specifically, the Examiner states, “Wagner teaches both a method of making a

set of arrays of fragments of DNA of interest and a method of providing a mixture of DNA fragments enriched in fragments that are characteristic of a phenotype of interest, which method includes providing affected DNA in fragmented form and providing unaffected DNA in fragmented form comprising the limitations set forth in claims 1, 2, 4-11, 14-16, 23-25, and 29..."

In response, Applicants respectfully submit that the methodology disclosed by Wagner, et al. is quite different from the instant invention inasmuch as the Wagner reference is directed to the detection of point mutations such as single base changes, utilizing a DNA mismatch binding protein (see e.g., the Abstract). The instant invention, as claimed, provides a methodology for obtaining mixtures of DNA fragments enriched in fragments are characteristic of a phenotype of interest, such is neither disclosed nor even suggested by Wagner, et al. which merely detects mutations.

In view of the foregoing, Applicants respectfully submit the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 1, 2, 4-11, 14-16, 23-25, and 27-30 under 35 U.S.C. § 102(e) as being "anticipated by Dong et al (US 2002/0142314 A1 October 03, 2002)."

In response, Applicants wish to point out that the instant application has an effective filing date of March 12, 1999, by virtue of its claimed priority of European Patent Application No. 99301933.0, from which PCT WO 00/55364 has claimed priority. The cited reference was based on an application filed June 12, 2001, which is clearly after this date. This, in turn, claims priority to an application filed October 27, 1999, also after the effective date of the instant application, and further claims priority to two provisional patent applications, one filed after the filing date of this application (May 26, 1999) and a second filed shortly before this application (October 27, 1998).

Inasmuch as the claim to 102(e) involves specific passages cited by the Examiner, Applicants are at a loss to determine whether any of these disclosures were contained in the October 27, 1998 provisional patent application filing. As such, Applicants is at a loss as to how to respond to the Examiner's rejection, inasmuch as only the disclosure of the original provisional patent application (60/105,867) could qualify as art under 35 U.S.C. § 102(e). Thus, without making any representation as to whether this patent publication is, in whole or in part, entitled to be cited as art under 35 U.S.C. § 102(e), Applicants will not comment until the Examiner demonstrates that the passages he has cited are relevant to and disclosed in the provisional patent application.

Applicants have obtained a copy of provisional patent application no. 60/105,867, filed on October 27, 1998. Applicants have reviewed the provisional application, and respectfully submit that it does not provide enabling disclosure for the invention of the breadth described and claimed in the Dong, et al. patent publication and further respectfully assert that it neither anticipates nor renders the instant invention obvious. Indeed, Applicants have reviewed the provisional application in light of the specific passages identified by the Examiner in the publication as being of particular interest, and find the following:

- (a) Regarding the claims: the provisional patent application does not contain any claims;
- (b) Regarding page 2, paragraph 37: there is no corresponding disclosure in the provisional patent application;
- (c) Regarding page 3, paragraph 50: the provisional application contains no figure analogous to Figure 2 of the publication, nor is there any analogous disclosure;
- (d) Regarding page 4, paragraphs 56–59: the provisional application contains no Figure 4, nor does it contain any analogous disclosure;

- (e) Regarding page 4, paragraph 64–67: the provisional application contains no figure analogous to Figure 8 of the publication, nor does it contain any analogous disclosures;
- (f) Regarding page 8, paragraph 84–88: the provisional application contains no analogous disclosure; and
- (g) Regarding page 9, paragraph 90–99, page 10, paragraph 110–113, page 11, paragraph 130–131 and page 12, paragraph 130–135: the provisional patent application contains no working examples or any analogous disclosure.

Applicants respectfully assert that the provisional application and the disclosure contained therein, which is the only disclosure which predates the filing to which the captioned application claims priority, neither anticipates nor even suggests the instant invention as recited in the claims. Applicants have appended hereto a copy of the provisional application, and respectfully invite the Examiner to review it to determine if there are any additional passages he would like to reference.

The Examiner has rejected claims 17, 18, 21 and 22 are rejected under 35 U.S.C. § 103(a) as being “unpatentable over Dong et al (US 2002/0142314 A1 October 03, 2002)”.

Appl. No. 09/914,604  
Amendment dated October 17, 2003  
Reply to Office action of May 21, 2003

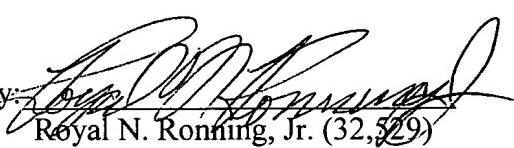
In response, Applicants reiterate the arguments above with regard to the impropriety of the citation of Dong, et al. as art under 35 U.S.C. § 102(e) and respectfully decline to comment on the rejection at this point.

In view of the foregoing, Applicants respectfully assert the Examiner's rejections cannot be sustained and should be withdrawn.

Applicants believe that the claims, as amended, are in allowable form and earnestly solicit their allowance. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on October 17, 2003.

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